510(k) Summary according to 21 CFR 807.92

APR - 5 2010

Applicants Name and Address:

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VP Processes, Quality & Regulatory Affairs

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Date submission was prepared:

March 2010

Device Name:

Trade Name:	Infinity Acute Care System Workstation Neonatal Care
Common Name:	Intensive Care Ventilator

Classification:

Class II

Regulation No.	Device	Product Code
Preferred Code:		
868.5895	Ventilator, continuous, facility use	73CBK
For predicates:		
868.5895	Ventilator, continuous, facility use	73CBK

Reason for the 510(k): Substantial Equivalence

Besides the more recent technological concept and modular approach, the functionality of the Infinity Acute Care System Workstation Neonatal Care is equivalent to Babylog 8000 and Evita XL Neo. Both intensive-therapy ventilators are intended to be used for neonates. The Evita XL ventilator is also used for the ventilation of pediatric patients.

Legally Marketed Device to which Substantial Equivalence is claimed:

510(k) number	Trade name	Company
K903089, K926292, K974176	Babylog 8000 plus	Dräger Medical AG & Co. KG
K961687, K983219, K980642 K992608, K010093, K051263, K072412	Evita XL	Dräger Medical AG & Co. KG

Executive Summary

This documentation covers the Infinity Acute Care System Workstation Neonatal Care as part of the Infinity Acute Care System (IACS).

The Infinity Acute Care System (IACS) is a modular and flexible solution for the acute point of care. It is designed to consist of different point-of-care specific workstations. All workstations consist of an Infinity Medical Cockpit, a standardized display and control unit for connected monitoring and therapy units.

The IACS Workstation Neonatal Care is intended to be used as integrated, networked, and configurable workstation to provide neonatal care specific therapy.

As of today, this workstation consists of the following main components with accessories and in combination with other devices:

- Infinity Medical Cockpit C500 and the
- Babylog VN500

The Infinity Medical Cockpit C500 is the control and display unit which runs a ventilation application. It enables setting of ventilation including alarms and displays patient ventilation monitoring data.

The Babylog VN500 provides neonatal care specific ventilation and monitoring data of ventilation parameters. It is intended for the ventilation of neonatal and pediatric patients.

General description of the device
The Infinity Acute Care System Workstation Neonatal Care provides Neonatal-Care specific functionality. It is made up of the ventilation unit Babylog VN500 and the Infinity Medical Cockpit C500.
The ventilation unit provides Neonatal-Care specific ventilation and monitoring data of ventilation parameters. The Infinity Medical Cockpit C500 is the control and display unit which runs a ventilation application. The patient monitoring data are displayed on the Infinity Medical Cockpit C500, which is also used to control ventilation settings including alarms.

Babylog VN500
The ventilation unit Babylog VN500 of the Infinity Acute Care System Workstation Neonatal Care is a microprocessor-controlled ventilator. The Babylog VN500 provides overpressure ventilation and adjustable oxygen concentration with pressure- and volume-controlled automatic and spontaneous breathing modes:

- pressure-controlled (**PC**):
  - o PC-SIMV (**S**ynchronized **I**ntermittent **M**andatory **V**entilation)
  - o PC-AC (**A**ssisted **C**ontrolled)
  - o PC-CMV (**C**ontinuous **M**andatory **V**entilation)
  - o PC-APRV (Option) (**A**irway **P**ressure **R**elease **V**entilation)
  - o PC-PSV (**P**ressure **S**upport **V**entilation)
  - o PC-MMV (**M**andatory **M**inute **V**olume Ventilation)
- Spontaneous (**Spn**):
  - o Spn-CPAP/VS (**C**ontinuous **P**ositive **A**irway **P**ressure / **V**entilation **S**upport)
  - o Spn-CPAP/PS (**C**ontinuous **P**ositive **A**irway **P**ressure / **P**ressure **S**upport)
  - o Spn-PPS (Option) (**P**roportional **P**ressure **S**upport)

Additionally the ventilation unit features special modes to complement the ventilation modes. If breathing of a spontaneously breathing patient stops, **Apnea Ventilation** switches over automatically to volume-controlled mandatory ventilation. **Automatic Tube Compensation ATC** reduces the breathing effort attributable to the tube. By switching on the **flow trigger**, the mandatory strokes are synchronised with the patient's spontaneous breathing attempts. **Inspiratoric termination** determines the duration of inspiration in PS, VS and PPS mode. It defines at which relation (in percent) of max. insp. flow the inspiration ends and the expiration starts. Atelectasis can be prevented by the **Sigh** function. **Auto release** determines the duration of pressure release using in PC-APRV mode.

Ventilation Application
The ventilation application software on the Infinity Medical Cockpit C500 is needed to allow the user to display and control all ventilation parameters of the ventilation unit. The combination of the ventilation software application on the Infinity Medical Cockpit C500, together with the Babylog VN500, provides the functionality of a complete ventilator (e.g. Evita XL).

The ventilation application supports simultaneous display of patient waveforms, parameter data, alarm display and annunciation, in addition to supporting graphical or textual display of historical data.
The Infinity Acute Care System can interface with specific Dräger Medical therapeutic and diagnostic equipment, as well as third party devices via a MEDIBUS data connection.

Infinity Medical Cockpit C500
The user interface of the Infinity Acute Care System Workstation Neonatal Care is the Infinity Medical Cockpit C500, a standardized display and control unit for the connected monitoring and therapy units.
The Infinity Medical Cockpit C500 is a standard platform, using common hardware, software, and user interface components to facilitate ease of use for clinicians.

Indications for Use

The Infinity Acute Care Systems Workstations Neonatal Care consist of monitoring and control displays and additional therapy units. They are intended to be used as integrated, networked, and configurable workstations to provide neonatal care specific therapy. The Infinity Acute Care Systems Workstations Neonatal Care are intended to be used by qualified and trained medical personnel.

The Infinity C Series Medical Cockpits, consisting of the C500 and the C700, are monitoring and control displays for the Infinity Acute Care System (IACS). Medical Cockpits are intended to be used to monitor waveforms, parameter information, and alarms as well as to control settings. The Infinity Series Medical Cockpits are intended to be used in environments where patient care is provided by trained healthcare professionals.

The Babylog VN500 ventilation unit of the Infinity Acute Care System is intended for the ventilation of neonatal patients from 0.4 kg (0.88 lbs) up to 10 kg (22 lbs) and pediatric patients from 5 kg (11 lbs) up to 20 kg (44 lbs) bodyweight. Babylog VN500 offers mandatory ventilation modes and ventilation modes for spontaneous breathing support and airway monitoring. The Babylog VN500 ventilation unit is used with Infinity C Series Dräger Medical Cockpits. The Babylog VN500 ventilation unit is intended for use in different medical care areas.

Babylog VN500 is intended for stationary use in hospitals and medical rooms or for patient transportation within the hospital.

List of performance testing:

Performance was tested in compliance with following standards:

IEC 60601-1 :2006	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 :2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-2-12:2001	Medical electrical equipment – Part 2-12: Particular Requirements for the safety of lung ventilators – critical care ventilators
IEC 60601-1-6 :2004	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard - Usability
IEC 60601-1-8:2006	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EN ISO 14971:2003	Medical devices - Application of risk management to medical devices
EN ISO 17664:2004	Sterilization of medical devices – information to be provided by the manufacturer for the reprocessing of resterilizable medical devices
FDA Guidance for Ventilators: 1995	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR - 5 2010

Drager Medical AG & Company KGAA
C/O Ms. Joyce Kilroy
Vice President
Drager Medical, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K093632
Trade/Device Name: Infinity Acute Care System Workstation Neonatal Care
Regulation Number: 21CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: March 15, 2010
Received: March 18, 2010

Dear Ms. Kilroy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 093632

Device Name: Infinity Acute Care System Workstation Neonatal Care

Indications for Use:

The Infinity Acute Care System Workstations Neonatal Care consist of monitoring and control displays and additional therapy units. They are intended to be used as integrated, networked, and configurable workstations to provide specific therapy in neonatal intensive care. The Infinity Acute Care System Workstations Neonatal Care are intended to be used by qualified and trained medical personnel.

The Infinity C Series Medical Cockpits, consisting of the C500 and the C700, are monitoring and control displays for the Infinity Acute Care System (IACS). Medical Cockpits are intended to be used to monitor waveforms, parameter information, and alarms as well as to control settings. The Infinity Series Medical Cockpits are intended to be used in environments where patient care is provided by trained healthcare professionals.

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Babylog VN500 is intended for stationary use in hospitals and medical rooms or for patient transportation within the hospital.

Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: 09 3632

(Posted November 13, 2003)